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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,656	04/18/2005	Ralf Wilhelm Schulte	129402.00101	9867

21269 7590 06/29/2007

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,656	SCHULTE ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1 and 5-31, drawn to a method of using one or more double-stranded oligoribonucleotides (dsRNA) to make an undisclosed composition for the specific modulation of the expression of target genes in cells and/or tissues of the CNS and/or eye of a subject.

Group II, Claims 2-31 and 46, drawn to a method of using a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) for the specific modulation of the expression of target genes in cells and/or tissues of the CNS and/or eye, wherein said composition is introduced into a cell, tissue or organism outside the blood-brain or blood-retina barrier.

Group III, Claims 32-39, drawn to a non-human organism comprising a cell or tissue comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA).

Group IV, Claim 40, drawn to a pharmaceutical composition comprising a double-stranded oligoribonucleotide (dsRNA).

Group V, Claim 41, drawn to a diagnostic composition for detecting a gene or gene expression involved in diseases of the CNS and/or eye.

Group VI, Claims 42-43, drawn to a method of identification and isolation of a drug capable of specific modulation of the expression of a target gene in cells and/or tissues of the eye.

Group VII, Claim 44, drawn to a method of using at least one composition of a structurally and functionally diverse genus of compositions for the specific modulation of expression of one or more target genes in cells and/or tissues of the CNS and/or eye.

Group VIII, Claim 45, drawn to a kit comprising at least one component of a structurally diverse genus of compositions.

Group IX, Claim 46, drawn to a method of using a cell comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) in drug discovery or target gene isolation and/or validation.

Group X, Claim 46, drawn to a method of using a non-human organism comprising a cell or tissue comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) in drug discovery or target gene isolation and/or validation.

Group XI, Claim 47, drawn to a method of using RNA interference for the diagnosis and/or therapy of disorders.

Group XII, Claim 47, drawn to a method of using a nucleic acid, carrier and /or vector for the diagnosis and/or therapy of disorders.

Group XIII, Claim 47, drawn to a method of using a non-human organism for the diagnosis and/or therapy of disorders.

Group XIV, Claim 47, drawn to a method of using a host cell or cell line for the diagnosis and/or therapy of disorders.

Group XV, Claim 47, drawn to a method of using a tissue or organ for the diagnosis and/or therapy of disorders.

2. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the special technical features of Groups I-II and XI are method steps to using one or more double-stranded RNAs for distinctly different purposes. The special technical feature of Group III and IX is a cell or tissue comprising a dsRNA. The special technical feature of Group IV is a composition comprising one or more double-stranded RNAs. The special technical features of Groups V-VIII are an unknown composition encompassed by the enormous genus of structurally and functionally diverse compositions. The special technical feature of Groups VI, X and XIII is a non-human organism. The special technical feature of Group XII is an undisclosed nucleic acid, carrier and vector. The special technical feature of Groups XIV and XV are host cells and tissues or organs, respectively.

3. **Should Applicant elect any of Groups I-II, V and VII, a further group restriction is required under 35 U.S.C. 121 and 372.** These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Claim(s) 1-2, 41 and 44 recite a plurality of structurally and functionally distinct neural tissues. These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is required to elect a

single disclosed neural tissue recited specifically in Claim(s) 1-2, 41 and 44 for prosecution on the merits to which the claims shall be restricted. Therefore, election is required inventive groups (a)-(b) below, wherein the modulation of target genes occurs, specifically:

a) in the cells and tissues of the eye,

b) in the cells and tissues of the central nervous system (CNS).

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the inventions lack the same or corresponding special technical features for the following reasons:

Inventive groups (a)-(b) are unrelated. The International Searching Authority has found the invention as it relates to the eye distinctly different from the invention as it relates to the central nervous system (CNS). One of ordinary skill in the art could readily consult any biology reference textbook (e.g., *Molecular Biology of the Cell*, Alberts et al., Garland Publishing; *Developmental Biology*, Gilbert, S., Sinauer Associates, Inc; *Gray's Anatomy of the Human Body*, Philadelphia: Lea and Febiger, 1918, New York: Bartleby.com, 2000) describing the structure, characteristics and biological properties for each of the tissues and organs, and would appreciate that based on such reference disclosures alone or in combination, that these tissues and organs are distinct and separate.

A reference rendering the eye as anticipated or obvious over the prior art would not necessarily also render CNS as anticipated or obvious over the prior art. Similarly, a finding that a method of administering a composition to the CNS was novel and unobvious over the prior art would not necessarily extend to a finding that a method of administering a composition to eye tissues was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature, a neural tissue, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the neural tissues does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed neural tissue, even though this requirement is traversed. Failure to elect a neural tissue from inventive groups (a)-(b) above consonant with Applicant's elected Invention may result in a notice of non-responsive amendment. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

It is further noted that this is a restriction requirement and should not be construed as an election of species.

Should Applicant elect any of Groups V and VII, a further restriction is required. The Group detailed above reads on patentably distinct inventions drawn to multiple compositions. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Claims 41 and 44 are drawn to an enormous genus of structurally and functionally diverse, as defined in Claims 1 to 26 that recite an enormous genus of structurally and functionally diverse dsRNA compositions, and Claims 32 to 39 that recite an enormous genus of cells, tissues and organisms. Similarly, the enormous genus of structurally and functionally diverse components recited in Claim 44 represents living and non-living matter.

A search for a dsRNA molecule would not be co-extensive with a search for CNS tissue. Further, a reference rendering an eye ball as anticipated or obvious over the prior art would not necessarily also render a transgenic organism as anticipated or obvious over the prior art. Similarly, a finding that a cell line was novel and unobvious over the prior art would not necessarily extend to a finding that a drug or carrier was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the

examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. The compounds/components are not regarded as being of similar nature because all of the alternatives do not share a common property or activity.

In response to the restriction requirement, Applicant must further elect for Group V a single composition selected from the group consisting of those compositions recited in Claims 1-26 and 32-39, and for Group VII one of the components from the list recited in Claim 44.

It is further noted that this is a restriction requirement and should not be construed as an election of species.

4. **Should Applicant elect any of Groups I-V and VII-XV, a species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of structurally diverse dsRNA molecules. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single dsRNA species from the genus of structurally and functionally distinct dsRNA species recited in Claims 13-19.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple dsRNA molecules that are structurally and functionally distinct. The numerous variations in the number, position and type of chemical modifications result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a dsRNA molecule that is an unmodified analogue of a target gene to have the same gene targeting efficiency and half-life as a chemically synthesized dsRNA molecule comprising chemical modifications to one or more nucleotides. Furthermore, Applicant contemplates some dsRNA molecules to be encoded by a transgene (Claim 19), which is necessarily mutually exclusive and chemically distinct from a dsRNA molecule that is chemically synthesized and comprising one or more chemically modified

nucleotides. Each of the dsRNA species comprises chemical features that confer unique, non-obvious, and distinctly different technical features onto the dsRNA that will directly impact the bioavailability, toxicity or bioactivity of the dsRNA.

A search for a chemically synthesized dsRNA would not be co-extensive with a search for a vector-encoded dsRNA. Further, a reference rendering a dsRNA molecule without a deletion, addition, substitution or modification to one or more nucleotides as anticipated or obvious over the prior art would not necessarily also render a dsRNA molecule with a deletion, addition, substitution or modification to one or more nucleotides as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. Given the breadth of the claimed, unrelated structures, a search for all possible species imposes an exceptional burden on the Office. As the technical feature, a dsRNA molecule, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 2, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 2.

Should Applicant elect any of Groups I-V and VII-XV, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims (Claim 20) directed to more than one species of promoters. These species are deemed to lack unity of invention because

they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single promoter species as recited in Claim 20, wherein the promoter is, specifically:

i) a cell-specific promoter, or

ii) a tissue-specific promoter.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple promoters that are structurally distinct. It is well known in the art that the numerous variations in the nucleic acid sequence of a promoter results in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a cell-type specific promoter, e.g. eye-specific, to be equally effective in regulating the expression of a gene in all other tissues of the body, e.g. the cerebellum. Each of the promoter species confers a unique, non-obvious, distinctly different technical feature onto the nucleic acid expression construct that will directly impact the cell-type specific expression of the dsRNA.

A search for an eye-specific promoter would not be co-extensive with a search for a CNS tissue-specific promoter. Further, a reference rendering an eye-specific promoter as anticipated or obvious over the prior art would not necessarily also render a CNS tissue-specific promoter as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature, a promoter, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must

also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 2, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 2.

Should Applicant elect any of Groups I-V and VII-XV, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of compositions to which the dsRNA is complexed. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single composition species to which the dsRNA is complexed from the list consisting of those compositions recited in Claims 22 and 23.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple compositions that are structurally distinct to which the dsRNA is complexed. The numerous compositions result in a vast genus of structurally unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a liposome to provide the same bioavailability as a cationic porphyrin. Similarly, one would not expect a fusogenic peptide to be as efficacious in the cell-type specific transport of a dsRNA molecule across a cell membrane as an adenovirus. Each of the species confers a unique, non-obvious, distinctly different technical feature onto the dsRNA molecule that will directly impact the bioavailability, toxicity or bioactivity of the dsRNA. Given the breadth of the claimed, unrelated structures, a search for all possible species imposes an exceptional burden on the Office.

A search for a liposome would not be co-extensive with a search for a fusogenic peptide. Further, a reference rendering an adenovirus as anticipated or obvious over the prior art would

not necessarily also render a cationic porphyrin as anticipated or obvious over the prior art. Similarly, a finding that a synthetic coat protein was novel and unobvious over the prior art would not necessarily extend to a finding that a cationic polyamine was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature, a dsRNA molecule, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 2, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 2.

Should Applicant elect any of Groups I-V and VII-XV, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of means by which the dsRNA molecule(s) is administered to the eyeball. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single administration means species from the list recited in Claim 26.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple administration method steps that are functionally distinct. The steps are not obvious variations of each other because one skilled in the art does not expect a method of systemic administration of a composition to achieve the same cell-type specific targeting of an eye-specific cell as direct retrobulbar administration. Each of the method steps confers a unique, non-obvious, distinctly different technical feature onto the overall method that will directly impact the bioavailability, toxicity or bioactivity of the dsRNA.

A search for iontophoresis would not be co-extensive with a search for eye drops. Further, a reference rendering eye drops as anticipated or obvious over the prior art would not necessarily also render systemic application as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature, dsRNA, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named administration species as listed in the cited claims to which the claims shall be restricted. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1 and 2, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1 and 2.

Should Applicant elect any of Groups III-VIII, X, XIII and XV, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of eye diseases. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single eye disease species, wherein the organism displays, specifically:

i) a disease of the inner segment of the eye ball, as recited in Claim 36,

ii) a retinal disease, as recited in Claim 37, or

iii) a degenerative retinal disease, as recited in Claim 38.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple retinal disease that are etiologically and pathologically distinct. A search for a degenerative retinal disease would not be co-extensive with a search for a disease of the inner segment of the eye ball. Further, a reference rendering a disease of the inner segment of the eye ball as anticipated or obvious over the prior art would not necessarily also render a degenerative retinal disease as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature, an eye, linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named eye disease species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claim 35, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 35.

Claims 2-4, 27-28, 33-38 and 41-47 and are generic to the following disclosed patentably distinct species: organisms, wherein Applicant contemplates a multitude of organisms (pg 14, ¶3; pg 16, ¶2; pg 17, lines 1-5). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed heterologous polynucleotide encoding a therapeutic molecule species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) and/or species election(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Q. JANICE LI, M.D.
PRIMARY EXAMINER